# 510(k) SUMMARY

MAR 5 2013

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirement of SMDA 1990 and 21 CFR 807.92.

## VIDAS® Lyme IgG

### A. Submitter Information


| | |
|---|---|
| Submitter's Name: | bioMérieux SA |
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| Date of Preparation: | September 2012 |


### B. Device Name

| | |
|---|---|
| Trade Name: | VIDAS® Lyme IgG |
| Common Name: | Lyme IgG Assay |
| Classification Name: | 21 CFR 866.3830 – Treponema pallidum treponemal test reagents |

### C. Predicate Device Name

Trade Name: Platelia™ Lyme IgG

### D. Device Description

The VIDAS Lyme IgG assay principle combines a two-step enzyme immunoassay sandwich method with a final fluorescent detection (ELFA). The Solid Phase Receptacle (SPR®) serves as the solid phase as well as the pipetting device for the assay. Reagents for the assay are ready-to-use and predispensed in the sealed reagent strips. All of the assay steps are performed automatically by the instrument. The reaction medium is cycled in and out of the SPR several times.

After a preliminary wash step and a sample dilution step, the sample is cycled in and out of the SPR. Antibodies to *B. burgdorferi* present in the specimen will bind to the *B. burgdorferi* antigen coating the interior of the SPR. Unbound sample components are washed away. Anti-human IgG antibodies conjugated with alkaline phosphatase will attach to the immunocomplex bound to the SPR wall. A final wash step removes unbound conjugate.

During the final detection step, the substrate (4-Methyl-umbelliferyl phosphate) is cycled in and out of the SPR. The conjugate enzyme catalyzes the hydrolysis of this substrate into a fluorescent product (4-Methyl-umbelliferone) the fluorescence of which is measured at 450 nm. The intensity of the fluorescence is proportional to the quantity of anti-*B. burgdorferi* IgG antibodies present in the sample. At the end of the assay, results are automatically calculated by the instrument. A test value is generated and a report is printed for each test.

## E. Intended Use

The VIDAS Lyme IgG (LYG) assay is an automated qualitative enzyme immunoassay intended for use on the instruments of the VIDAS family in the presumptive detection of human IgG antibodies to *Borrelia burgdorferi* in human serum (plain or separation gel) or plasma (sodium heparin or lithium heparin). It should be used to test patients with a history and/or symptoms of infection with *B. burgdorferi*. All VIDAS Lyme IgG positive specimens should be further tested with a Western Blot IgG assay to obtain supportive evidence of infection with *B. burgdorferi*.

## F. Technological Characteristics Summary

A general comparison of the similarities and differences of the assays is presented in the table below.

| Item | VIDAS® Lyme IgG (LYG) Assay | Platelia™ Lyme IgG (K080012) |
|---|---|---|
| **Intended Use** | The VIDAS Lyme IgG (LYG) assay is an automated qualitative enzyme immunoassay intended for use on the instruments of the VIDAS family in the presumptive detection of human IgG antibodies to *Borrelia burgdorferi* in human serum (plain or separation gel) or plasma (sodium heparin or lithium heparin). It should be used to test patients with a history and/or symptoms of infection with *B. burgdorferi*. All VIDAS Lyme IgG positive specimens should be further tested with a Western Blot IgG assay to obtain supportive evidence of infection with *B. burgdorferi*. | The Platelia™ Lyme IgG Test is a qualitative test intended for use in the presumptive detection of human IgG antibodies to *Borrelia burgdorferi* in human serum or plasma (K3 EDTA, sodium heparin or sodium citrate). The EIA system should be used to test serum or plasma from patients with a history and symptoms of infection with *B. burgdorferi*. All positive and equivocal specimens should be re- tested with a specific, second-tier test such as Western-Blot. Positive second- tier results are supportive evidence of infection with *B. burgdorferi*. The diagnosis of Lyme disease should be made based on history and symptoms (such as *erythema migrans*), and other laboratory data, in addition to the presence of antibodies to *B. burgdorferi*. Negative results (either first or second-tier) should not be used to exclude Lyme disease. |
| **Specimen** | Serum or plasma | Serum or plasma |
| **Analyte** | IgG antibodies to *Borrelia burgdorferi* | IgG antibodies to *Borrelia burgdorferi* |
| **Automated** | Yes | No |
| **Assay Technique** | Enzyme-linked fluorescent assay (ELFA) | Enzyme immunoassay (EIA) |

## G. Nonclinical Tests

A summary of the non-clinical results is presented below.

### Precision

For the precision study, 4 serum samples were tested in duplicate in 40 different runs (2 runs per day over 20 days) with 2 reagent lots at 1 site (n = 80). The precision was calculated following the recommendations of the CLSI® document EP5-A2. The total precision data in the table reflect the 80 values generated per sample for Site 1 and takes into account replicate, run, day, calibration, and lot as potential sources of variation. The total precision for controls include within-day, between-days and between-calibration variability and is lot specific.

| Panel Member | N | Mean Index | Within-run | | Within-day | | Between-days | | Total | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | SD | CV (%) | SD | CV (%) | SD | CV (%) | SD | CV (%) |
| Negative | 80 | 0.11 | 0.01 | 9.7 | 0.00 | 3.8 | 0.01 | 5.4 | 0.02 | 18.5 |
| High Negative | 80 | 0.15 | 0.02 | 11.2 | 0.01 | 5.3 | 0.00 | 0.0 | 0.03 | 18.3 |
| Low Positive | 80 | 0.26 | 0.01 | 4.3 | 0.01 | 3.8 | 0.01 | 2.4 | 0.02 | 6.8 |
| High Positive | 80 | 2.34 | 0.09 | 3.7 | 0.05 | 2.3 | 0.07 | 3.0 | 0.13 | 5.7 |
| Positive Control | 40 | 0.45 | NA | NA | 0.03 | 5.9 | 0.01 | 1.4 | 0.03 | 6.7 |
| Negative Control | 40 | 0.00 | NA | NA | 0.00 | 0.0 | 0.00 | 0.0 | 0.00 | 0.0 |

### Reproducibility

For reproducibility, 4 serum samples were tested in duplicate in 40 different runs (2 runs per day over 20 days) with 2 reagent lots at 3 sites (n =240). The reproducibility was calculated following the recommendations of the CLSI® document EP5-A2. The total reproducibility data in the table reflects the 240 values generated per sample for all sites and takes into account replicate, run, day, calibration, lot, and site as potential sources of variation. Out of the 240 total values, 2 high negatives gave a positive value and 2 low positives gave a negative value. The total reproducibility for controls include within-day, between-days, between-calibration and between-site variability and is lot specific.

| Panel Member | N | Mean Index | Within-run | | Within-day | | Between-days | | Between-site | | Total | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | SD | CV (%) | SD | CV (%) | SD | CV (%) | SD | CV (%) | SD | CV (%) |
| Negative | 240 | 0.11 | 0.01 | 7.6 | 0.00 | 4.3 | 0.00 | 3.8 | 0.00 | 0.0 | 0.02 | 15.5 |
| High Negative | 240 | 0.15 | 0.01 | 8.6 | 0.00 | 3.3 | 0.00 | 0.0 | 0.00 | 0.0 | 0.02 | 15.5 |

| Panel Member | N | Mean Index | Within-run | | Within-day | | Between-days | | Between-site | | Total | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | SD | CV (%) | SD | CV (%) | SD | CV (%) | SD | CV (%) | SD | CV (%) |
| Low Positive | 240 | 0.26 | 0.01 | 5.4 | 0.01 | 3.9 | 0.00 | 1.6 | 0.00 | 0.0 | 0.02 | 7.7 |
| High Positive | 240 | 2.31 | 0.10 | 4.1 | 0.04 | 1.8 | 0.03 | 1.2 | 0.02 | 0.8 | 0.12 | 5.3 |
| Positive Control | 120 | 0.45 | NA | NA | 0.02 | 5.2 | 0.00 | 0.0 | 0.00 | 0.0 | 0.03 | 6.3 |
| Negative Control | 120 | 0.00 | NA | NA | 0.00 | 0.00 | 0.00 | 0.0 | 0.00 | 0.0 | 0.00 | 0.0 |

## Interfering Substances

**Specimen-related Interference:** Interferences were studied according to the recommendations of CLSI® document EP7-A2. None of the following factors have been found to significantly influence this assay:
- hemolysis (hemoglobin: 5 g/L (monomer)),
- lipemia (lipids: 30 g/L equivalent in triglycerides),
- bilirubinemia (bilirubin: 0.3 g/L),
- human albumin (albumin up to 60 g/L).

It is recommended not to use samples that are hemolyzed, lipemic or icteric and, if possible, to collect a new sample.

**Exogenous Interferents:** the potential interferences with 15 commonly used drugs were studied: no interference was observed at the concentration tested.

| Drug | Concentration tested | Drug | Concentration tested |
|---|---|---|---|
| Acetylsalicylic Acid | 3.62 mmol/L | Ibuprofen | 2425 µmol/L |
| Amoxicillin | 206 µmol/L | Minocycline | 4.1 µmol/L |
| Azithromycin | 34 µmol/L | Penicillin G | 240 000 U/L |
| Betamethasone | 8.31 µmol/L | Penicillin Phenoxymethyl | 30 000 U/L |
| Ceftriaxone | 1460 µmol/L | Prednisolone | 8.31 µmol/L |
| Cefuroxime Axetil | 1416 µmol/L | Roxithromycin | 15.3 µmol/L |
| Doxycycline Hyclate | 16.1 µmol/L | Tetracyclines | 67.5 µmol/L |
| Erythromycin | 22.2 µmol/L | | |

## H. Clinical Testing

### Sensitivity testing

202 retrospective samples from patients meeting a case definition of LD and confirmed positive for *B. Burgdorferi* infection were run on the VIDAS Lyme IgG assay and the predicate Lyme IgG assay.
For the predicate test, equivocal results were considered as positive for the evaluation. The following results were obtained:

| Stage | N | VIDAS Lyme IgG % Sensitivity | Predicate Lyme IgG % Sensitivity | Difference in proportions |
|---|---|---|---|---|
| **Stage I** (early localized, single lesion) 1 – 30 days | 119 | 49.60 95% CI[(1)] [40.3% – 58.9%] | 42.90 95% CI [33.8% – 52.3%] | +6.7% 95% CI [(-6)% – (19)%] |
| **Stage II** (early disseminated, multiple lesions) 1 – 30 days | 61 | 83.60 95% CI [71.9% – 91.8%] | 54.10 95% CI [40.8% – 66.9%] | +29.5% 95% CI [(14)% – (45)%] |
| **Stage III** (late disseminated) | 22 | 90.90 95% CI [70.8% – 98.9%] | 72.70 95% CI [49.8% – 89.3%] | +18.2% 95% CI [(-4)% – (40)%] |
| **All stages** | 202 | 64.40 95% CI [57.3% – 71.0%] | 49.50 95% CI [42.4% – 56.6%] | +14.9% 95% CI [(5)% – (24)%] |

(1) 95% Confidence Interval.

### Method Comparison

A prospective study was performed on 975 fresh or frozen prospectively collected sera submitted for routine Lyme disease testing from an endemic area of the United States. Testing was performed in three laboratories.
At each laboratory, the samples were tested in parallel using a commercially available Lyme IgG EIA method (predicate) and the VIDAS Lyme IgG assay. Positive % Agreement (PPA) is calculated for the positives and equivocals together since the 2-tier testing does not make a distinction and calls for both of them to be tested by Western Blot. Combined results from the three sites are shown below:

| N = 975 | Predicate Lyme IgG | | |
|---|---|---|---|
| **VIDAS Lyme IgG** | **Positive** | **Equivocal** | **Negative** |
| **Positive** | 77 | 17 | 36 |
| **Negative** | 18 | 15 | 812 |
| **Total** | 95 | 32 | 848 |
| **Positive % Agreement 95% CI** | 74.0 % (94/127) [65.5% - 81.4%] | | |
| **Negative % Agreement 95% CI** | 95.8 % (812/848) [94.2% - 97.0%] | | |

**Second-Tier Testing**: In accordance with the CDC recommendations for use of a 2-tier Lyme disease testing scheme, the VIDAS Lyme IgG positive results and the predicate Lyme IgG positive and equivocal results were confirmed using a commercially available Lyme IgG Western Blot method. The percent agreement between VIDAS and predicate Lyme IgG positives and the percent agreement between VIDAS–predicate–Western Blot IgG positives and Predicate–Western Blot IgG positives is shown below.

| | 1st Tier + or ± | IgG Western Pos. | IgG Western Neg. |
|---|---|---|---|
| **Predicate IgG** | 127 | 63 | 64 |
| **VIDAS IgG** | 130 | 65 | 65 |
| **VIDAS IgG and Predicate IgG** | 94 | 62 | 32 |

1st tier PPA = 74.0 % (94/127) [95% CI; 65.5% - 81.4%]
2nd tier PPA = 98.4% (62/63) [95% CI; 91.47 – 99.96]

**Analytical Specificity**

100 sera from apparently healthy subjects from an endemic population (New York) and 100 sera from a non-endemic population (Texas) with no known history of Lyme disease were run on the VIDAS Lyme IgG assay and the predicate Lyme IgG assay. The following results were obtained:

| | VIDAS | | Predicate | |
|---|---|---|---|---|
| | **Positivity** | **Negativity** | **Positivity(1)** | **Negativity** |
| **Endemic** | 3.0% | 97.0% | 3.0% | 97.0% |
| **Non-Endemic** | 0.0% | 100.0% | 1.0% | 99.0% |

(1) Includes positives and equivocals.

**CDC Reference Panel**

The following information is from a serum panel obtained from the CDC and tested using the VIDAS Lyme IgG kit. The results are presented as a means to convey further information on the performance of this assay with a masked, characterized serum panel. This does not imply an endorsement of the assay by the CDC.

| Time from onset | VIDAS Lyme IgG | | | Western Blot IgG | | |
|---|---|---|---|---|---|---|
| | **Positive** | **Negative** | **Agreement with clinical status** | **Positive** | **Negative** | **Agreement with clinical status** |
| **Normals** | 0 | 5 | 100.0 % (5/5) | 0 | 5 | 100.00 % (5/5) |
| **< 1 month** | 2 | 3 | 40.0 % (2/5) | 2 | 3 | 40.00 % (2/5) |
| **1 – 2 months** | 4 | 2 | 66.6 % (4/6) | 0 | 6 | 0.00 % (0/6) |
| **3 - 12 months** | 8 | 8 | 50.0 % (8/16) | 7 | 9 | 43.75% (7/16) |
| **> 1 year** | 7 | 0 | 100.0 % (7/7) | 7 | 0 | 100.00 % (7/7) |
| **Total** | 21 | 18 | 66.6 % (26/39) | 16 | 23 | 53.84% (21/39) |

**Cross-Reactivity**

Cross-reactivity is based on the study of samples that are negative with the test being evaluated and positive for the potentially interfering disease. The results of the samples tested according to the disease are shown in the table below:

| Infection or Diagnosis | N | VIDAS Lyme IgG positive results | % Cross-reactivity |
|---|---|---|---|
| **Anti Nuclear Antibodies** | 60 | 5 | 8.33 |
| **C Reactive Protein** | 61 | 2 | 3.28 |
| **Cytomegalovirus** | 40 | 0 | 0.00 |
| **Epstein Barr Virus** | 34 | 0 | 0.00 |
| ***Helicobacter Pylori*** | 143 | 2 | 1.40 |
| **Hepatitis A Virus** | 150 | 3 | 2.00 |
| **Herpes Simplex Virus** | 125 | 1 | 0.80 |
| **Human Immunodeficiency Virus** | 20 | 1 | 5.00 |
| **Human Anti-mouse Antibodies** | 43 | 0 | 0.00 |
| **Leptospirosis** | 206 | 6 | 2.91 |
| **Measles** | 38 | 0 | 0.00 |
| **Mumps** | 46 | 0 | 0.00 |
| **Rheumatoid Factor** | 28 | 0 | 0.00 |
| **Rickettsiosis** | 133 | 3 | 2.25 |
| **Rubella** | 19 | 0 | 0.00 |
| **Syphilis** | 256 | 1 | 0.39 |
| **Systemic Lupus Erythematosus** | 28 | 2 | 7.14 |
| **Toxoplasmosis** | 26 | 1 | 3.85 |
| **Varicella Zoster Virus** | 58 | 0 | 0.00 |

The effect of Babesiosis, Erhlichiosis and Rocky Mountain spotted fever pathologies on the VIDAS Lyme IgG performance is not known.

**I. Conclusion**

The results from the nonclinical and clinical studies submitted in this premarket notification are complete and demonstrate that the VIDAS® Lyme IgG is substantially equivalent to the predicate device identified in Item C of this summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

bioMerieux SA
c/o Catherine FRITSCH
Regulatory Affairs Director
5 rue des Aqueducs
69290 Craponne, France

March 5, 2013

Re: K122986
Trade/Device Name: VIDAS® Lyme IgG
Regulation Number: 21 CFR 866.3830
Regulation Name: Treponema pallidum treponemal test reagents
Regulatory Class: Class II
Product Code: LSR
Dated: January 25, 2013
Received: January 28, 2013

Dear Ms. FRITSCH:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K122986

Device Name: VIDAS® Lyme IgG

Indications For Use:

The VIDAS Lyme IgG (LYG) assay is an automated qualitative enzyme immunoassay intended for use on the instruments of the VIDAS family in the presumptive detection of human IgG antibodies to *Borrelia burgdorferi* in human serum (plain or separation gel) or plasma (sodium heparin or lithium heparin). It should be used to test patients with a history and/or symptoms of infection with *B. burgdorferi*. All VIDAS Lyme IgG positive specimens should be further tested with a Western Blot IgG assay to obtain supportive evidence of infection with *B. burgdorferi*.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)